COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Addendum to the 2015 COT statement on potential risks from polybrominated diphenyl ethers (PBDEs) in the infant diet: potential risks from polybrominated diphenyl ethers (PBDEs) in the diets of infants and young children

Background

1. The Scientific Advisory Committee on Nutrition (SACN) is undertaking a review of scientific evidence that will inform the Government's dietary recommendations for infants and young children. SACN is examining the nutritional basis of the advice. The Committee on Toxicity in Food, Consumer Products and the Environment (COT) was asked to review the risks of toxicity from chemicals in the diet of infants, most of which has been completed, and young children. The reviews will identify new evidence that has emerged since the Government's recommendations were formulated, and will appraise that evidence to determine whether the advice should be revised. The recommendations cover diet from birth to age five years, but are being considered in two stages, focussing first on infants aged 0 to 12 months, and now on advice for children aged 1 to 5 years.

2. In 2015 the COT issued a statement on potential risks from polybrominated diphenyl ethers (PBDEs) in the infant diet[1]. This addendum to the 2015 statement updates the PBDE exposures for infants because new data have become available, and provides exposure assessments for children aged 1 to 5 years. There are currently no Government dietary recommendations for infants and young children that relate to PBDEs.

3. The COT previously assessed the risks associated with exposure to PBDEs in the infant diet in 2015, using the $BMDL_{10}$ values and corresponding reference points for behavioural changes observed in adult mice given PBDE congeners by gavage neonatally. The reference points are 172 ng/kg bw /day, 4.2 ng/kg bw/day, 9.6 ng/kg bw/day and 19640 ng/kg bw/day, for BDE-47, BDE-99, BDE-153 and BDE-209, respectively. No new toxicological data had emerged since the 2015 statement that warrant revision of these reference points.

[1] http://cot.food.gov.uk/sites/default/files/PBDEstatementfinal.pdf

4. EFSA (2011) considered that in interpreting the MOEs, potential inter and intra-species kinetic differences had been accounted for when using a body burden comparison between humans and animals, taking the higher end of the reported range for elimination half-life in humans. EFSA also concluded that individual differences in susceptibility had been accounted for, as the body burden used was that associated with a $BMDL_{10}$ for neurobehavioural effects in mice induced during a relevant period for brain development, considered the most vulnerable population. EFSA therefore concluded that an MOE greater than 2.5 would indicate that there was unlikely to be a concern for health. The COT previously concluded that '*inter-species differences in toxicokinetics were accounted for by the body burden approach, and that the use of a relatively high elimination half-life for humans, and of data relating to a critical period of development, reduced uncertainties in the risk assessment. However, they considered that MOEs should be rather higher than 2.5 to provide assurance of safety'.*

PBDE exposures in infants and young children aged 0 months to 5 years

New data on sources of PBDE exposure

5. There were no new data for PBDE levels in breast milk in the UK. Occurrence data used for estimating exposure from human milk in the 2015 COT statement were used to estimate exposure from this route in this paper.

6. PBDEs comprise ten homologues with a total of 209 isomeric congeners. BDE-209 is evaluated separately as it has a higher reference point, is fully brominated and has different pharmacokinetics (EFSA 2011).

Table 1: PBDE homologues and congeners (from EFSA, 2011)

Homologues	Chemical formula	Molecular mass	Isomeric congeners	Number of congeners
monoBDEs	$C_{12}H_9BrO$	249.1	BDE-1 to BDE-3	3
diBDEs	$C_{12}H_8Br_2O$	328.0	BDE-4 to BDE-15	12
triBDEs	$C_{12}H_7Br_3O$	406.9	BDE-16 to BDE-39	24
tetraBDEs	$C_{12}H_6Br_4O$	485.8	BDE-40 to BDE-81	42
pentaBDEs	$C_{12}H_5Br_5O$	564.7	BDE-82 to BDE-127	46
hexaBDEs	$C_{12}H_4Br_6O$	643.6	BDE-128 to BDE-169	42
heptaBDEs	$C_{12}H_3Br_7O$	722.5	BDE-170 to BDE-193	24
octaBDEs	$C_{12}H_2Br_8O$	801.4	BDE-194 to BDE-205	12
nonaBDEs	$C_{12}HBr_9O$	880.3	BDE-206 to BDE-208	3
decaBDE	$C_{12}Br_{10}O$	959.2	BDE-209	1

7. The concentrations of selected BDEs (BDE-17, -28, -47, -49, -66, -71, -77, -85, -99, -100, -119, -126, -138, -153, -154, -183 and 209*)*, based on the availability of authentic standards, the composition of technical PBDE mixtures and/or their occurrence in the environment and in food, in different

varieties of infant formula and commercial infant foods have been measured recently in an FSA Survey (Rose *et al., 2015*). The most recent measurements of PBDEs in other foods sampled in the UK were for the composite food groups of the 2012 Total Diet Study (TDS) (Fernandes *et al.,* 2012).

8. There were no new UK data on PBDE levels in indoor air, therefore a value of 24 pg/m^3 was used for exposure estimates, as in the 2015 COT statement. This value was the median summed concentration of BDEs 28, 47, 49, 66, 99, 100, 153, and 154, in air sampled in 31 UK homes (reported in 2006), which was higher than in outdoor air (median 8.7 pg/m^3) (Harrad *et al*., 2010). Concentrations of BDE-209 were not reported.

9. There were no new UK data on PBDE levels in dust. Occurrence values were taken from 30 samples of dust vacuumed from carpets or bare floors in UK homes (Harrad *et al*., 2008) (Table 8). No data were found on PBDEs in soil.

Exposure

10. Detailed assessments have been performed for the dietary sources of exposure to PBDEs. Exposure assessments of potential non-dietary sources (i.e. dust and air) have also been provided.

11. Consumption data (for food and water) (on a bodyweight basis) from the Diet and Nutrition Survey in Infants and Young Children (DNSIYC) (DH, 2013) and data from the National Diet and Nutrition Survey Rolling Programme years 1-4 (NDNS) (Bates *et al*., 2014) have been used for the estimation of dietary exposure. Body weight data used in the estimation of other PBDE exposures are summarised in Table 2.

Table 2: Average body weights used in exposure assessments when individual body weights were not available.

Age bands (months)	Bodyweight
0 - <4	5.9 kg[a]
≥4 - <6	7.8 kg[b]
≥6 - <9	8.7 kg[b]
≥9 - <12	9.6 kg[b]
≥12 - <15	10.6 kg[b]
≥15 - <18	11.2 kg[b]
≥18 - <24	12.0 kg[c]
≥24 - <60	16.1 kg[c]

[a] *DH, 1994*
[b] *DH, 2013.*
[c] *Bates et al., 2014.*

Dietary Exposure

Breast milk

12. Estimated exposures of exclusively breastfed infants, aged 0 to 6 months are those that were reported in the 2015 COT statement (Table 3). Data on breast milk consumption in older infants and young children up to the age of 18 months became available from the DNSIYC survey and were used in estimating exposure from breast milk in the 6-18 months age groups based on the maximum levels of PBDEs (Table 3). There were too few records of breast milk consumption for children older than 18 months in NDNS to allow a reliable exposure assessment, and breast milk is expected to contribute minimally in this age group.

13. Mean and high level exposure estimates for BDE 47, 99 and 153 ranged from 3.3-70 and 6.8-100 ng/kg bw/day, respectively. For BDE 209, mean and high level exposure estimates ranged from 0.92-5.0 and 1.9-7.4 ng/kg bw/day, respectively for the different age groups.

Table 3. Estimated exposure to PBDEs from breastmilk.

Congener (concentrations in µg/kg whole weight)	PBDE exposure from breast milk (ng/kg bw/d) by age group (months)											
	0 - <4[a]		4 - <6[a]		6 - <9[b]		9 - <12[b]		12 - <15[b]		15 - <18[b]	
	Mean	High-level	Mean	High-level	Mean	High-level[c]	Mean	High-level[c]	Mean	High-level[c]	Mean	High-level[c]
BDE 47 (513)	70	100	53	79	34	79	20	59	15	39	13	27
BDE 99 (131)	18	27	13	20	8.7	21	5.0	15	3.9	9.8	3.3	6.8
BDE 153 (156)	21	32	16	24	10	25	5.9	18	4.6	12	4.0	8.1
BDE 209 (36.4)	5.0	7.4	3.7	5.6	2.4	5.8	1.4	4.2	1.1	2.7	0.92	1.9

[a] *Mean and high level PBDE exposures at ages 0 - <6 months were based on exclusive breastfeeding and consumption of 800 and 1200mL, respectively (COT, 2015).*
[b] *Consumption data from DNSIYC.*
[c] *High-level is 97.5th percentile*
Values rounded to 2 significant figures (SF).

Infant formula

14. Possible PBDE exposure levels from infant formula were calculated for infants up to 6 months of age assuming exclusive feeding on formula (Table 4). Exposure estimates were derived using the occurrence data for 'comfort milk' infant formula from Rose *et al.* (2015) due to its relevance for 0 to 6 month old infants. Exposures to BDEs 47, 99 and 153 based on consumption of 800mL or 1200mL formula, were up to 0.18 ng/kg bw/day. Exposure to the sum of 16 BDEs excluding BDE 209 was up to 1.2 ng/kg bw/day

Table 4. Estimated exposures to PBDEs from exclusive feeding on infant formula aged 0 to <6 months.

Congener	PBDE exposures from infant formula (ng/kg bw/day)			
	0 - <4 months		4 - <6 months	
	800 mL[a]	1200 mL[a]	800 mL[a]	1200 mL[a]
BDE 47	0.12	0.18	0.092	0.14
BDE 99	0.12	0.18	0.092	0.14
BDE 153	0-0.041	0-0.061	0-0.031	0-0.046
Sum excluding 209[b]	0.24-0.81	0.37-1.2	0.18-0.62	0.28-0.92
BDE 209	3.2	4.7	2.4	3.6

Values rounded to 2 SF, expressed as LB to UB[2] range where appropriate.
[a] Mean and high level exposures were based on exclusive feeding on infant formula and consumption of 800 and 1,200mL, respectively (COT, 2015).
[b] Sum of BDE-17, -28, -47, -49, -66, -71, -77, -85, -99, -100, -119, -126, -138, -153, -154 and -183. The UB concentrations used for calculating exposure to the sum of BDEs (excluding BDE 209) were derived by adding the individual LOD values (0.002 µg/kg) for each congener that was not detected.

15. Exposures of infants and children aged 4.0 to <18 months from infant formula were also estimated using DNSIYC consumption data (DH 2013) (Table 5) and summary data for the concentrations reported in the Rose *et al* (2015) study for all types of infant formula. For BDEs 47, 99 and 153, the lowest LB to highest UB mean and 97.5th percentile exposures from infant formula ranged from 0.00-0.13 and 0.00-0.28 ng/kg bw/day, respectively. For

[2] The upper bound (UB) approach uses the value of the LOQ or LOD concentration for data that were < LOQ/LOD. The lower bound (LB) approach uses the value zero for data that were < LOQ/LOD

the sum of all tested BDEs excluding BDE 209, the lowest LB to the highest UB mean and 97.5th percentile exposures ranged from 0.10-2.1 and 0.00-4.5 ng/kg bw/day, respectively. For BDE 209, the lowest LB to the highest UB mean and 97.5th percentile exposures ranged from 0.04-0.40 and 0.19-0.84 ng/kg bw/day, respectively.

Commercial Infant Foods

16. Table 6 summarises the total exposure from commercial infant foods to PBDEs estimated for infants and young children up to 18 months using DNSIYC consumption data (DH 2013). For BDEs 47, 99 and 153, the lowest LB to the highest UB mean and 97.5th percentile exposures ranged from 0.00-0.05 and 0.00-0.19 ng/kg bw/day, respectively. For the sum of all BDEs excluding BDE 209, the lowest LB to the highest UB mean and 97.5th percentile exposures ranged from 0.01-0.49 and 0.05-1.8 ng/kg bw/day, respectively. For BDE 209, the lowest LB to the highest UB mean and 97.5th percentile exposures ranged from 0.09-0.43 and 0.64-1.7 ng/kg bw/day, respectively.

Table 5: Estimated exposure to PBDEs from infant formula as part of the diet for ages 4 to <18 months.

Congener	LB to UB[a] dietary exposure to PBDEs (ng/kg bw/day) by age group (months)									
	4 - <6		6 - <9		9 - <12		12 - <15		15 - <18	
	Mean	P97.5[b]	Mean	P97.5[b]	Mean	P97.5[b]	Mean	P97.5[b]	Mean	P97.5[b]
BDE 47	0.00065-0.13	0.0077-0.28	0.0013-0.11	0.0042-0.22	0.0013-0.078	0.023-0.18	0.00019-0.030	0.00-0.14	0.00015-0.017	0.00-0.085
BDE 99	0.00078-0.13	0.0083-0.28	0.0015-0.11	0.0046-0.22	0.0016-0.078	0.029-0.18	0.00025-0.030	0.00-0.14	0.00019-0.017	0.00-0.085
BDE 153	0.000028-0.13	0.000057-0.28	0.00015-0.10	0.00023-0.22	0.00019-0.077	0.0018-0.18	0.0000095-0.030	0.00-0.14	0.000024-0.017	0.00-0.085
Sum excluding 209[c]	1.1-2.1	0.020-4.5	0.56-1.7	0.011-3.5	0.58-1.2	0.075-2.9	0.16-0.48	0.00-2.2	0.10-0.27	0.00-1.6
BDE 209	0.039-0.40	0.32-0.84	0.14-0.35	0.46-0.76	0.14-0.28	0.43-0.69	0.053-0.10	0.27-0.44	0.032-0.054	0.19-0.31

Values rounded to 2 SF.

[a] *Treating occurrence data < LOD as 0 and as the LOD, respectively.*

[b] *97.5th percentile*

[c] *Sum of BDE-17, -28, -47, -49, -66, -71, -77, -85, -99, -100, -119, -126, -138, -153, -154 and -183.* The UB concentrations used for calculating exposure to the sum of BDEs (excluding BDE 209) were derived by adding the individual LOD values (0.002 µg/kg) for each congener that was not detected.

Table 6: Estimated exposures to PBDEs from commercial infant foods at age 4 to <18 months.

Congener	LB to UB[a] dietary exposure to PBDEs (ng/kg bw/day) by age group (months)									
	4 - <6		6 - <9		9 - <12		12 - <15		15 - <18	
	Mean	P97.5[c]	Mean	P97.5[c]	Mean	P97.5[c]	Mean	P97.5[c]	Mean	P97.5[c]
BDE 47	0.011-0.039	0.047-0.17	0.014-0.052	0.055-0.18	0.012-0.045	0.057-0.19	0.006-0.024	0.033-0.12	0.0030-0.013	0.020-0.066
BDE 99	0.0050-0.031	0.019-0.14	0.006-0.042	0.024-0.15	0.005-0.036	0.026-0.16	0.003-0.019	0.015-0.092	0.001-0.010	0.0090-0.051
BDE 153	0.000-0.020	0.000-0.092	0.000-0.028	0.00-0.11	0.000-0.025	0.00-0.10	0.000-0.013	0.000-0.071	0.000-0.0080	0.000-0.044
Sum excluding 209[b]	0.024-0.36	0.11-1.6	0.032-0.49	0.12-1.8	0.028-0.44	0.12-1.8	0.015-0.23	0.074-1.2	0.0070-0.13	0.046-0.72
BDE 209	0.25-0.30	1.2-1.4	0.37-0.43	1.4-1.6	0.33-0.39	1.5-1.7	0.18-0.21	1.1-1.2	0.091-0.11	0.64-0.72

Values rounded to 2 SF.

[a] *Treating occurrence data < LOD as 0 and as the LOD, respectively.*

[b] *Sum of BDE-17, -28, -47, -49, -66, -71, -77, -85, -99, -100, -119, -126, -138, -153, -154 and -183.* The UB concentrations used for calculating exposure to the sum of BDEs (excluding BDE 209) were derived by adding the individual LOD values for each congener that was not detected.

[c] *97.5th percentile*

Other foods (from TDS)

17. Mean and high-level estimates of infant dietary exposure to PBDEs from foods other than commercial infant foods were previously calculated using measurements for the 19 composite food groups analysed in the 2012 TDS in combination with data on the consumption of those foods from DNSIYC. Table 7 summarises LB and UB dietary exposures to PBDEs for 4 to 60 month old children, from those TDS data together with consumption data from the DNSIYC (DH 2013) and NDNS (Bates et al., 2014).

18. For BDEs 47, 99 and 153 individually, the mean and 97.5th percentile exposures in infants ranged from 0.23-1.1 and 0.61-3.7 ng/kg bw/day, respectively (Table 7). The corresponding mean and 97.5th percentile exposures of 12 to 60 month old children ranged from 0.10-0.69 and 0.18-1.6 ng/kg bw/day, respectively. For the sum of all BDEs excluding BDE 209, the lowest LB to the highest UB mean and 97.5th percentile exposures in infants ranged from 2.7-3.2 and 6.9-9.8 ng/kg bw/day, respectively. The corresponding range in 12 to 60 month old children was 1.6-3.2 and 1.3-6.7 ng/kg bw/day, respectively. For BDE 209, the lowest LB to the highest UB mean and 97.5th percentile exposures in infants ranged from 1.3-4.5 and 4.1-11 ng/kg bw/day, respectively. The corresponding range in 12 to 60 month old children was 5.9-9.4 and 12-20 ng/kg bw/day, respectively.

19. For BDEs 47, 99 and 153, and the sum of BDEs excluding BDE 209 the food group contributing most to total exposure was dairy products. For BDE 209, the groups making the largest contributions to total exposure were in the order milk > miscellaneous cereals (includes foods such as pasta, bakery products, rice) > sugars (e.g. jam, marmalade, and jelly) in children up to 24 months and milk > sugars > miscellaneous cereals for 24 to 60 month old children.

Table 7: Estimated exposure to PBDEs from food in young children aged 4 to 60 months.

Congener	LB to UB[a] dietary exposure to PBDEs (ng/kg bw/day) by age group (months)									
	4-<12 [b]		12 - <15		15 - <18		18 - <24		24 - <60	
	Mean	P97.5[c]	Mean	P97.5[c]	Mean	P97.5[c]	Mean	P97.5[c]	Mean	P97.5[c]
BDE-47	1	2.5-3.4	0.61	1.5	0.61	1.4	0.69	1.4	0.57	1.1
BDE-99	1-1.1	2.6-3.7	0.53	1.6	0.54	1.3	0.57	1.3	0.45	0.80
BDE-153	0.23-0.25	0.61-0.86	0.13	0.36	0.13	0.29	0.14	0.31	0.10	0.18
Sum excluding 209[d]	2.7-3.2[e]	6.9-9.8[e]	1.7-3.0	4.2-6.0	1.7-3.1	1.3-1.4	1.9-3.2	3.9-6.7	1.6-2.5	3.0-4.6
BDE-209	1.3-4.5[e]	4.1-11[e]	5.9-7.9	12-15	6.4-8.8	12-16	6.8-9.4	16-20	5.9-8.3	13-15

Values rounded to 2 SF.

[a] *Treating occurrence data < LOD as 0 and as the LOD, respectively. If there is only one figure all data were > LOD.*

[b] *Range of values for different infant ages from COT 2015.*

[c] 97.5th percentile

[d] *Sum of BDE-17, -28, -47, -49, -66, -71, -77, -85, -99, -100, -119, -126, -138, -153, -154 and -183.* The UB concentrations used for calculating exposure to the sum of BDEs (excluding BDE 209) were derived by adding the individual LOD values for each congener that was not detected.

[e] *Based on the lowest LB and the highest UB for the different infant age ranges from COT 2015.*

Environmental exposures to PBDEs

Dust and soil

19. Exposure to BDEs 47, 99, 153 and 209 through ingestion of dust (and soil) were updated assuming ingestion of 60 mg dust and soil per day for 6 to 12 month old children and 100 mg per day between the ages of 12-60 months (US EPA, 2011), based on the mean and maximum concentrations reported (Table 7)). Children of these age groups are likely to consume more soil and dust than younger infants who are less able to move around and come into contact with soil and dust. Since there were no data for soil, it has been assumed that the levels could be comparable to those in dust. However, this is a conservative assumption because the presence of PBDEs in dust is likely to be due to their use as flame retardants and hence higher than levels in soil.

20. Since the dust was sampled in 2006, and there have been changes in usage of PBDEs since then, it is possible that these estimates are not representative of current exposures. Exposures of up to 21000 ng/kg bw/day were calculated for BDE 209 when using the maximum reported concentration of 2200 mg/kg for this congener.

Table 8: Estimated exposure to PBDEs from dust and soil in infants and young children aged aged 6 to 60 months.

Congener (mean and max concentrations in µg/kg)	6- <9 months		9 - <12 months		12 - <15 months		15 - <18 months		18 - <24 months		24 - <60 months	
	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]
BDE 47 (15, 58)	0.10	0.40	0.09	0.36	0.14	0.55	0.13	0.52	0.13	0.48	0.09	0.36
BDE 99 (36,180)	0.25	1.2	0.22	1.1	0.34	1.70	0.32	1.6	0.30	1.5	0.22	1.1
BDE 153 (14,110)	0.10	0.76	0.09	0.69	0.13	1.0	0.13	0.98	0.12	0.92	0.09	0.68
BDE 209 (260000, 2200000)	1800	15000	1600	14000	2500	21000	2300	20000	2200	18000	1600	14000

Values are rounded to 2 SF.
[a] Congener present at mean measured concentration.
[b] Congener present at maximum measured concentration.

Air

21. The estimated exposures to the sum of BDEs (28, 47, 49, 66, 99, 100, 153, and 154) from air that were reported for infants in the 2015 COT statement are updated in Table 8, together with estimated exposure for 12-60 month old children, on the basis of ventilation rates for infants and young children (US EPA, 2011) using the median reported occurrence value of 24 pg/m^3. The exposure to the sum of BDEs via air ranged from 0.013 to 0.018 ng/kg bw/day.

Table 9: Estimated exposure to PBDEs from air.

ΣPBDE[a] excl. 209 median concentration	**Air exposure to PBDEs (ng/kg bw/d) by age group (months)**							
	0 - <4 (3.6)[b]	**4 - <6 (4.1)[b]**	**6 - <9 (5.4)[b]**	**9 - <12 (5.4)[b]**	**12 - <15 (8.0)[b]**	**15 - <18 (8.0)[b]**	**18 - <24 (8.0)[b]**	**24 - <60 (10.1)[b]**
24 pg/m^3	0.015	0.013	0.015	0.014	0.018	0.017	0.016	0.015

[a]*Sum of BDEs 28, 47, 49, 66, 99, 100, 153 and 154*
[b]*Ventilation rate in m^3/day*

Risk Characterisation

22. Potential risks from the exposure of infants and young children to PBDEs were characterised by margins of exposure (MOEs), calculated as the ratio of the reference points to the estimated exposures for dietary and non-dietary sources. The reference points used were 172 ng/kg bw /day, 4.2 ng/kg bw/day, 9.6 ng/kg bw/day and 19640 ng/kg bw/day, for BDE-47, BDE-99, BDE-153 and BDE-209, respectively. MOEs of somewhat above 2.5 would be considered of low concern (COT, 2015).

23. Table 10 shows MOEs for exposure via breast milk at age 0 to 18 months. The MOEs for BDE-209 all exceed 3000 and therefore would not be considered to indicate a cause for concern. The MOEs for BDE-47 range from 2 to 10 and those for BDE-99 and -153 are less than 2, indicating a potential health concern in the latter cases.

24. Table 11 summarises the MOEs for the exposure to PBDEs from infant formula at age 0 to 18 months. The MOEs for BDE-47 and BDE-209 are at least 800. BDE-153 has MOEs ranging from 40 to 5000 and BDE-99 has MOEs that range from 20 to 2000.

25. Table 12 summarises the MOEs for exposure from commercial infant foods. For BDE-47 the MOEs are all greater than 900 and for BDE-209 the MOEs are greater than 20000. The MOEs for BDE-99 range from 30 to 4000 and those for BDE-153 range from 90 to 1000.

Table 10. MOEs for exposure to PBDEs from consumption of breast milk. MOE's in **bold** indicate a potential concern.

Congener	0 - <4 months[a]		4 - <6 months[a]		6 - <9 months[b]		9 - <12 months[b]		12 - <15 months[b]		15 - <18 months[b]	
	Mean	High level	Mean	High level	Mean	High level[c]	Mean	High level[c]	Mean	High level[c]	Mean	High level[c]
BDE 47	3	**2**	3	**2**	5	**2**	9	3	10	5	10	7
BDE 99	**0.2**	**0.2**	**0.3**	**0.2**	**0.5**	**0.2**	**0.8**	**0.3**	**1**	**0.4**	**1**	**0.6**
BDE 153	**0.5**	**0.3**	**0.6**	**0.4**	**0.9**	**0.4**	**2**	**0.5**	**2**	**0.8**	**2**	**1**
BDE 209	4000	3000	5000	4000	8000	3000	10000	5000	20000	7000	20000	10000

All MOEs are rounded to 1 SF.

[a] *Mean and high level PBDE exposures at ages 0-<6 months were based on exclusive breastfeeding and consumption of 800 and 1,200mL, respectively (COT, 2015).*

[b] *Consumption data from DNSIYC.*

[c] *High-level is 97.5th percentile*

Table 11. MOEs for exposure to PBDEs from infant formula

Congener	MOEs by age group (months) based on UB[a] to LB[b] exposures											
	0 – 4 months[c]		4 - <6 months[c]		6 - <9 months[d]		9 - <12 months[d]		12 - <15 months[d]		15 - <18 months[d]	
	Mean	High level	Mean	High level	Mean	High level[e]	Mean	High level[e]	Mean	High level[e]	Mean	High level[e]
BDE 47	1000	1000	2000	1000	2000-200000	800-40000	2000-200000	1000-7000	≥6000	≥10000	≥10000	≥2000
BDE 99	40	20	50	30	40-2000	20-800	50-2000	20-100	≥100	≥30	≥200	≥40
BDE 153	200	200	300	200	≥ 90	≥ 40	≥ 100	50-5000	≥300	≥70	≥600	≥100
BDE 209	6000	4000	8000	5000	60000-100000	30000-40000	70000-100000	30000-50000	200000 400000	40000-70000	400000 600000	60000-100000

All MOEs are rounded to 1 SF.

Where ≥ values are provided these are based on u*pper bound estimates of exposure, as lower bound exposures were zero and therefore MOEs would be infinite.*

[a] *Upper bound*

[b] *Lower bound*

[c] *Mean and high level PBDE exposures at ages 0-<6 months were based on exclusive feeding on infant formula and consumption of 800 and 1,200mL, respectively (COT, 2015).*

[d] *Consumption data from DNSIYC.*

[e] *High-level is 97.5th percentile*

Table 12. MOEs for exposures to PBDEs from commercial infant foods.

Congener	MOEs by age group (months) based on UB[a] to LB[b] exposure									
	4 - <6 months		6 - <9 months		9 - <12 months		12 - <15 months		15 - <18 months	
	Mean	P97.5[e]	Mean	P97.5[e]	Mean	P97.5[e]	Mean	P97.5[e]	Mean	P97.5[e]
BDE 47	4000-20000	1000-4000	3000-10000	900-3000	4000-10000	900-3000	7000-30000	1000-5000	10000-60000	3000-9000
BDE 99	100-800	30-200	100-700	30-200	100-800	30-200	200-1000	50-300	400-4000	80-500
BDE 153	≥500[c]	≥100[c]	≥ 300[c]	≥90[c]	≥400[c]	≥90[c]	≥700[c]	≥100[c]	≥1000[c]	≥ 200[c]
BDE 209	70000-80000	10000-20000	50000[d]	10000[d]	50000-60000	10000[d]	90000-100000	20000[d]	20000-200000	30000[d]

All MOEs are rounded to 1 SF.

[a] *Upper bound.*

[b] *Lower bound.*

[c] Where ≥ values are provided these are based on u*pper bound estimates of exposure, as lower bound exposures were zero and MOEs would be infinite.*

[d] *Only one value is shown when the rounded MOEs derived from upper and lower bound exposures have the same value*

[e] *97.5th percentile*

26. Table 13 shows the MOEs for exposures from foods other than commercial infant foods for infants and young children aged 4 to 60 months. The MOEs for BDE-99 range from 3 to 9, other than in the 97.5th percentile of exposure for those aged 4 to >12 months (MOE = 1), whilst those for BDE-153 range from 10 to 90. MOEs for BDE-47 all exceed 50, whilst those for BDE-209 are all greater than 1000.

Table 13. MOEs for exposures to PBDEs from food (TDS)

Congener	MOEs by age group (months) based on UB to LB[a] exposure									
	4-<12 months		12-<15 months		15-<18 months		18-<24 months		24-<60 months	
	Mean	P97.5[b]	Mean	P97.5	Mean	P97.5	Mean	P97.5	Mean	P97.5
BDE-47	200[c]	50-70	300	100	300	100	200	100	300	200
BDE-99	4	1	8	3	8	3	7	3	9	5
BDE-153	40	10-20	80	30	80	30	70	30	90	50
BDE-209	4000-20000	2000-5000	2000-3000	1000-2000	2000-3000	1000-2000	2000-3000	1000	2000-3000	1000-2000

All MOEs are rounded to 1 SF.
[a] Upper bound to lower bound.
[b] 97.5th percentile
[c] Only one value is shown when the rounded MOEs derived from the range of values for different infant age groups, or the upper and lower bound exposures have the same value

27. Table 14 shows the MOEs for exposures to PBDEs from ingestion of dust and soil for infants and children aged 6 to 60 months. For BDE-99 the MOEs range from 3 to 20. For BDE-209 the MOEs calculated using the maximum concentration in dust range from 0.9 to 1, and using the mean concentration they are 8 to 10. The MOEs for BDE-99 range from 3 to 10, for BDE-153 they range from 10 to 100. All MOEs for BDE-47 exceed 300.

28. As concluded previously by the COT, the analysis indicated possible concerns regarding exposure of infants to BDE-47, -99 and -153 via breast milk, although there is perhaps less concern for BDE 47. This conclusion is unaltered, as there are no new data on PBDEs in breastmilk of mothers in the UK. The new data on concentrations of PBDEs in infant formula and in commercial infant foods do not indicate a concern for dietary exposure. The COT previously concluded that infant exposure to BDE-99 and -153 from foods other than commercial infant food, indicated a possible concern. The current analysis does not indicate any such concern in young children aged 1-5 years from this source of exposure.

29. Also as concluded previously by the COT, the analysis indicated possible concerns regarding exposure to BDE-209 via dust (and soil) if this congener is present at the maximum reported concentrations in household dust. Exposure from this source is likely to be overestimated due to the assumption that the concentrations of PBDEs in soil could be similar to those in dust.

30. In principle the risk assessment should take into account aggregate exposure from all sources. However, a meaningful assessment of aggregate exposure for the PBDEs could not be conducted as different congeners were measured in different media ,the relative potencies of most congeners is unknown and it is uncertain whether all congeners share the same mode of action. Using the lower bound approach, the sum of BDEs-47, -99 and -153 is in the region of 60-80% of the sum of BDE-17, -28, -47, -49, -66, -71, -77, -85, -99, -100, -119, -126, -138, -153, -154 and -183.

31. Since PBDEs are no longer used, exposure would be expected to decrease over time. Bramwell et al. (2014) noted that there had been a moderate reduction in PBDE levels in breast milk since the UK ban, however the study was of limited size (n=6). A similar downward trend was reported in Sweden by Lind et al (2003) in a study looking at the changes in PBDE levels in breast milk from 1996 to 2001 (93 samples from 1996-1999 and 31 samples for 2000-2001). Fängström et al (2008) reported that individual PBDE congeners in breast milk samples from Sweden showed different patterns over a study period of 1980 to 2004. BDE-47 and -99 reached a peak in the middle of the 1990s and subsequently showed declining levels, whereas BDE-153 levels were increasing until 2001 whereafter they stabilised.

32. In a study by Domingo (2008) in Northeast Spain the dietary intake estimate for PBDEs from food samples collected in 2006 was reported as 75 ng/day; this was a reduction from 97 ng/day from samples collected in 2000. Newton et al. (2015) found that indoor and ventilation system air samples taken in 2012 from homes, offices, shops and schools in Sweden had generally lower PBDE concentrations than were found in a previous study performed in 2006. The occurrence of PBDEs in the atmosphere was studied in two urban and two rural sites in the UK over the period of 2000-2010 by Birgul et al. (2012). They reported a peak in PBDE concentrations for the years 2001-2003 followed by a decline in the subsequent years studied. This is in agreement with EFSA (2011) who reported that levels in the environment have been declining since the international agreements on bans and regulations on production and use of technical mixtures were introduced.

33. Bramwell et al. (2014) also reported a modest reduction in serum PBDE concentrations in the UK, when samples from 20 subjects taken between 2011 and 2012 were compared against samples taken in 2003 from 154 subjects. This date range is consistent with that found in other studies on PBDE’s.

Table 14. MOEs for exposure to PBDEs from consumption of dust and soil. MOE's in **bold** indicate a potential concern.

Congener	6- <9 months		9 - <12 months		12 - <15 months		15 - <18 months		18 - <24 months		24 - <60 months	
	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]	Mean[a]	Max[b]
BDE 47	2000	400	2000	500	1000	300	1000	300	1000	400	2000	500
BDE 99	20	3	20	4	10	3	10	3	10	3	20	4
BDE 153	100	10	100	10	70	10	70	10	80	10	100	10
BDE 209	10	**1**	10	**1**	8	**0.9**	9	**1**	9	**1**	10	**1**

All MOEs are rounded to 1 SF.

[a] *Congener present at mean measured concentration (Table 7).*

[b] *Congener present at maximum measured concentration (Table 7).*

Conclusions

34. Exposure to PBDEs occurs from its previous use as a flame retardant and subsequent release into the environment. The major sources of exposure for infants and young children are breast milk and household dust.

35. The risks associated with exposure of infants and young children to PBDEs are assessed in this addendum in relation to reference values of 172 ng/kg bw /day, 4.2 ng/kg bw/day, 9.6 ng/kg bw/day and 19640 ng/kg bw/day, for BDE-47, BDE-99, BDE-153 and BDE-209, respectively.

36. The 2015 COT statement indicated a possible concern with respect to exposure of infants to BDE-99 and (to a lesser extent) BDE-153 from food, other than commercial infant food. The current analysis indicated that exposure of young children aged 1-5 years to these congeners from such food was unlikely to be a health concern.

37. This new analysis for young children indicates a potential concern for BDE-99 and -153 exposure from breast milk at age 12-18 months, and for exposure to BDE-99 and -209 in dust and soil in children aged 1-5 years. These conclusions are consistent with the 2015 COT statement relating to infant exposure.

38. Exposures from infant formula and from commercially produced infant food are lower and are unlikely to be a health concern.

39. There are 209 PBDE congeners, many of which have not been tested for their toxicological properties. Individual congeners have differing persistence and therefore toxicity tests performed with previously available commercial technical mixtures are of limited relevance to that in the environment and the food profile of PBDEs. Only four congeners have suitable reference points and can be used for risk assessment.

40. There are a number of uncertainties in the estimates of exposure to PBDEs and in their toxicological effects. Information on these can be found in the previous COT Statement.

41. As PBDEs are no longer used commercially, levels would be expected to decrease over time and moderate reductions in levels have been reported for breast milk, food and indoor and outdoor air over the last decade or two.

42. Given that potential concerns are for exposures from breast milk, food and household dust, options for risk management are limited. Continued monitoring should occur to ensure that levels are declining as expected.

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